

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference see form PCT/ISA/220		FOR FURTHER ACTION See paragraph 2 below
International application No. PCT/GB2005/000944	International filing date (day/month/year) 10.03.2005	Priority date (day/month/year) 11.03.2004
International Patent Classification (IPC) or both national classification and IPC B65D83/14, B05B11/00, A61M15/08		
Applicant GLAXO GROUP LIMITED		

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:	Authorized Officer
 European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx. 523656 epmu d Fax: +49 89 2399 - 4465	Azaïzia, M Telephone No. +49 89 2399-6960



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2005/000944

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - a sequence listing
 - table(s) related to the sequence listing
 - b. format of material:
 - in written format
 - in computer readable form
 - c. time of filing/furnishing:
 - contained in the international application as filed.
 - filed together with the international application in computer readable form.
 - furnished subsequently to this Authority for the purposes of search.
3. In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

Box No. II Priority

1. The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43bis.1 and 64.1) is the claimed priority date.
2. This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
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Box No. IV Lack of unity of invention

1. In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:
 - paid additional fees.
 - paid additional fees under protest.
 - not paid additional fees.
2. This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
 - complied with
 - not complied with for the following reasons:

see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
 - all parts.
 - the parts relating to claims Nos.

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-29, 48-51
	No:	Claims	30-47, 52, 53
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-53
Industrial applicability (IA)	Yes:	Claims	1-53
	No:	Claims	

2. Citations and explanations

see separate sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2005/000944

Box No. VI Certain documents cited

1. Certain published documents (Rules 43bis.1 and 70.10)
and / or
2. Non-written disclosures (Rules 43bis.1 and 70.9)

see form 210

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Re Item IV

Lack of unity of invention

The present application lacks unity (Rule 13.1 PCT), as 6 groups of inventions are claimed:

- **INVENTION 1: Independent claim 1 and its dependent claims 2-29:**

A fluid dispensing device comprising essentially a finger-operable actuator member configured such that a minimum actuating force is required to be applied to said actuator member to cause dispensing of a fluid product.

- **INVENTION 2: Independent claim 30 and its dependent claims 31-36:**

A fluid dispensing device comprising essentially a finger-operable actuator member having a stop to provide alignment of at least one cam surface of said actuator member and at least one cam follower surface of a dispensing member.

- **INVENTION 3: Independent claim 37 and its dependent claims 38-41:**

A fluid dispensing device comprising essentially a releasable detent mechanism for selectively holding a finger-operable actuator member in outward and inward positions.

- **INVENTION 4: Independent claim 42 and its dependent claims 43-47:**

A fluid dispenser, adapted for dispensing a fluid product into the nasal cavity of a user, essentially comprising a nozzle, a housing and a fastening mechanism which fastens the nozzle in an opening of said housing.

- **INVENTION 5: Independent claim 48 and its dependent claims 49-51:**

A set of component parts for manufacturing a plurality of fluid dispensers for dispensing a fluid product into a nasal cavity of a user, the set essentially comprising a plurality of identical nozzles and a plurality of housings each having a different characteristic from the others.

- **INVENTION 6: Independent claim 52 and its dependent claim 53:**

A fluid dispenser, adapted for dispensing a fluid product into the nasal cavity of a user, essentially comprising a nozzle made from a different material than the housing of said fluid dispenser.

(A) The following common concept linking together the independent claims 1, 30 and 37 is not novel, see for example document WO-A-03/095007 which already discloses (the references in parentheses applying to this document) a fluid dispensing device (405, shown in fig.19) for dispensing a fluid product having:

- a dispensing outlet (415) from which the fluid product is dispensable,
- a supply (430) of the fluid product,

- a dispensing member (440) mounted for movement in a dispensing direction along an axis which causes a dose of the fluid product in the supply to be dispensed from the dispensing outlet (415), and

- at least one finger-operable actuator member (420,421) mounted for movement in an actuating direction which is generally transverse to the axis,

- wherein the actuator member (420,421) has at least one cam surface (the cooperating surfaces of the levers 420, 421) and the dispensing member (440) has at least one cam follower surface (425a,425b),

- wherein the actuator member (420,421) is movable in the actuating direction to cause the at least one cam surface (the cooperating surfaces of the levers 420, 421) to bear against the at least one cam follower surface (425a,425b) to cam the dispensing member (440) in the dispensing direction to cause the fluid product dose to be dispensed from the dispensing outlet (415).

(B) The following common concept linking together the independent claims 42, 48 and 52 is not novel, see for example document US-A-4 860 738 which already discloses (the references in parentheses applying to this document) a fluid dispenser (110, shown in fig.6-8) adapted for dispensing a fluid product into the nasal cavity of a user having a separate nozzle (124) sized and shaped for insertion into a nostril of the user and a housing (112) in which the fluid product is containable, wherein the housing has an opening (opening of the extended portion 129) in which the nozzle is received (see c.5, l.38-41).

(C) In addition, no corresponding special technical features are present in claims 1, 30, 37, 42, 48 and 52, so that the technical relationship between the subject-matter of these claims required by Rule 13.2 PCT is lacking, and the requirement for unity of invention referred to in Rule 13.1 PCT is not fulfilled. The features of each group which are not common with any of the other groups address indeed different objective technical problems. Said problems may be regarded as being:

- a) to guarantee the production of an effective spray (the commitment and drive sections of independent claim 1);
- b) to ensure a "ready-to-use" configuration of the fluid dispensing device (the stop of independent claim 30);
- c) to assist in assembly of the fluid dispensing device (the opening and the releasable detent mechanism of independent claim 37);

- d) to permit testing of the pharmaceutical performance of the nozzle while the development and design of the housing continues (the nozzle secured to the housing by the fastening mechanism of independent claim 42);
- e) to customise the fluid dispensing device for different markets and/or products (the identical nozzles and the different housings of independent claim 48);
- f) to customise the nozzle for insertion into a nostril and/or for contacting a fluid product while keeping the manufacturing costs as low as possible (the nozzle made of a different material than the housing of independent claim 52).

Therefore, the requirement of unity is not fulfilled (Rule 13.1 PCT), because there are no common special technical features (Rule 13.2 PCT).

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

- D1: WO-A-03/095007 (2003-11-20), cited by the applicant.
- D2: WO-A-02/20168 (2002-03-14)
- D3: US-A-5 899 365 (1999-05-04)
- D4: US-A-4 860 738 (1989-08-29)
- D5: FR-A-2 671 294 (1992-07-10)
- D6: US-A-2002/170928 (2002-11-21)
- D7: WO-A-99/49984 (1999-10-07)
- D8: US-B1-6 305 371 (2001-10-23)
- D9: US-B1-6 382 205 (2002-05-07)

2. INDEPENDENT CLAIM 1

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of independent claim 1 does not involve an inventive step in the sense of Article 33(3) PCT.

2.1 The document **D1**, which is considered to represent the most relevant state of the art, discloses (see **Re Item IV**, paragraph (A) - see also **D1**, p.33-34, fig. 19, 19a, 19b) a fluid dispensing device (fig.19) from which the subject-matter of claim 1 differs in that the

commitment and drive sections of the at least one cam surface are provided on the finger-operable actuator member instead of the dispensing member (440), whereas the at least one cam follower is provided on the dispensing member instead of the finger-operable actuator member (420).

It is generally known to the person skilled in the art that these distinguishing features of claim 1 are equivalent to the features of document **D1** and can be interchanged where circumstances make it desirable. The skilled person would regard it a normal design procedure. Consequently, the subject-matter of independent claim 1 lacks an inventive step (Article 33(3) PCT).

2.2. The additional features of dependent claims 2-29 are EITHER already known from **D1**, OR represent merely one of several straightforward technical possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill. Consequently, dependent claims 2-19 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step (Article 33(3) PCT).

3. INDEPENDENT CLAIM 30

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of independent claim 30 is not new in the sense of Article 33(2) PCT.

3.1 The document **D2** discloses (the references in parentheses applying to this document) a fluid dispensing device (fig.3-6) for dispensing a fluid product having:

- a dispensing outlet (2) from which the fluid product is dispensable,
- a supply (3) of the fluid product,
- a dispensing member (8) mounted for movement in a dispensing direction along an axis which causes a dose of the fluid product in the supply to be dispensed from the dispensing outlet, and
- a finger-operable actuator member (5) mounted for movement in an actuating direction which is generally transverse to the axis,
- wherein the actuator member has at least one cam surface (6) and the dispensing member has at least one cam follower surface (7),
- wherein the actuator member (5) is movable in the actuating direction to cause the at least one cam surface (6) to bear against the at least one cam follower surface (7) to cam the dispensing member (8) in the dispensing direction to cause the fluid product

dose to be dispensed from the dispensing outlet (see especially fig.4), and
- wherein the actuator member further has a stop (the tip portion of a nose section of the actuator member 5, see especially fig.3) to stop the dispensing member (8) being movable along the axis in a direction opposite the dispensing direction beyond a predetermined axial position to provide alignment of the least one cam surface (6) and the at least one cam follower surface (7).

The subject-matter of claim 30 is therefore not new (Article 33(2) PCT).

- 3.2 The subject-matter of independent claim 30 is also not new (Article 33(2) PCT) with regard to the disclosure of the documents **D3** and/or **D4** (see the corresponding passages cited in the search report) since the curved surface 12 formed on each shell-like member 9 of **D3** (see fig.3,5,6) and/or the camming surface 175 of **D4** (see fig.8) perform also the task of stopping the dispensing container in a rest position.
- 3.3 The additional features of dependent claims 31-36 are already known from **D2**, **D3** and/or **D4** (see the corresponding passages cited in the search report) so that the subject-matter of these claims also lacks novelty (Article 33(2) PCT).

4. INDEPENDENT CLAIM 37

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of independent claim 37 is not new in the sense of Article 33(2) PCT.

- 4.1 The document **D2** further discloses (the references in parentheses applying to this document) an actuator member (5) which is movable:
 - from an **outward position** with respect to the housing (1), which enables the dispensing container (3) to be inserted through an access opening (situated at the bottom of the housing 1) to a rest position (shown in fig.3) in the housing (1); This **outward position** being the position of the actuator member 5 when said actuator member 5 is completely dislodged from the housing 1;
 - to an **inward position** (shown in fig.3-6) with respect to the housing (1), which prevents the dispensing container (3) being inserted through the access opening to the rest position in the housing (1), but from which **inward position** the actuator member (5) is able to be moved inwardly with respect to the housing (1) to cause a dispensing container (3) disposed in the rest position (shown in fig.3) to move to the dispensing position (shown in fig.4);

- the fluid dispensing device further having a releasable detent mechanism (the small protrusions on the sidewalls of the actuator member 5, see especially fig.5 and fig.6) for selectively holding the actuator member (5) in its outward and inward positions.

The subject-matter of claim 37 is therefore not new (Article 33(2) PCT).

- 4.2 The subject-matter of independent claim 37 is also not new (Article 33(2) PCT) with regard to the disclosure of the documents **D3**, **D4** and/or **D5** (see the corresponding passages cited in the search report).
- 4.3 The additional features of dependent claims 38-41 are already known from **D2**, **D3**, **D4** and/or **D5** (see the corresponding passages cited in the search report) so that the subject-matter of these claims also lacks novelty (Article 33(2) PCT).

5. INDEPENDENT CLAIM 42

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of independent claim 42 is not new in the sense of Article 33(2) PCT.

- 5.1 The document **D6** discloses (the references in parentheses applying to this document) a fluid dispenser (see fig.63-65) adapted for dispensing a fluid product into the nasal cavity of a user having a nozzle (8) sized and shaped for insertion into a nostril of the user and a housing (102) in which the fluid product is containable, wherein the housing (102) has an opening (17) in which the nozzle (8) is received and a fastening mechanism (see p.8, §[0135]) which fastens the nozzle (8) in the opening (17). The subject-matter of claim 42 is therefore not new (Article 33(2) PCT).
- 5.2 The additional features of dependent claims 43-47 are already known from **D6** (see p.8, §[0135], Fig.63-65) so that the subject-matter of these claims also lacks novelty.

6. INDEPENDENT CLAIM 48

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 48-51 does not involve an inventive step in the sense of Article 33(3) PCT.

- 6.1 In the technical field of medical fluid dispensers, it is already known to the skilled person to use colour and/or shape codings for identifying, among a plurality of fluid dispensers,

a particular fluid dispenser containing a particular medicament to be administered (see for example **D8** (cf. c.1, l.43-57) and/or **D9** (cf. c.3, l.58-l.61)). Consequently, the subject-matter of claims 48-51 appears to lack an inventive step (Article 33(3) PCT).

7. INDEPENDENT CLAIM 52

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of independent claim 52 is not new in the sense of Article 33(2) PCT.

7.1 The document **D6** discloses (the references in parentheses applying to this document) a fluid dispenser (see fig.63-65) adapted for dispensing a fluid product into the nasal cavity of a user having:

- a nozzle (8) which can be made of a hard plastic or a more pliant material, such as silicone (see p.14, §[0185]); and
- a housing which is made of polypropylene (PP), polyethylene (PE) or other thermoplastic material that can be molded (see p.12, §[0175]).

The subject-matter of claim 52 is therefore not new (Article 33(2) PCT).

7.2 The subject-matter of independent claim 52 is also not new (Article 33(2) PCT) with regard to the disclosure of the document **D7** (see p.7, l.11-l.15 and l.28-l.29 - p.11, l.11 to p.12, l.8 - figures 2-4).

7.3 The additional features of dependent claim 53 are already known from **D6** and/or **D7** so that the subject-matter of this claim also lacks novelty (Article 33(2) PCT).

8. The subject-matter of claims 1-53 is considered industrially applicable since it can be made or used in any kind of industry (Article 33(4) PCT), such as the medical industry for example.

Re Item VI

Certain documents cited

Certain published documents

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.
PCT/GB2005/000944

Application No Patent No	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO 2004/080606	23.09.2004	11.03.2004	
Application No Patent No	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO 2005/028007	31.03.2005	21.09.2004	23.09.2003

Re Item VII

Certain defects in the international application

9. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents **D2-D9** is not mentioned in the description, nor are these documents identified therein.
10. The independent claims are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art being placed in the preamble and with the remaining features being included in the characterising part (Rule 6.3(b)(i) and (ii) PCT).
11. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
12. If matter in the document **D1** referred to on page 1, line 19 of the description (i.e. the document "incorporated by reference") is essential to satisfy the requirements of Article 5 PCT, the usual expression "which is hereby incorporated by reference", and/or any other similar expression, should be deleted and, instead, the said matter should be expressly incorporated into the description, because the application should, regarding the essential features of the invention, be self-contained, i.e. capable of being understood without reference to any other document.